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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HEATHER WANKE, MIA JONES, and JANICE NEWMAN,

Plaintiffs,

v.

INVASIX INC.,

Defendants.

CASE NO.

COMPLAINT FOR:

1. **BREACH OF WARRANTY**
2. **VIOLATION OF CALIFORNIA UNFAIR COMPETITION STATUTE, BUS. &PROF. CODE § 17200 et seq.**
3. **VIOLATION OF CALIFORNIA FALSE ADVERTISING LAW, BUS. & PROF. CODE § 17500 et seq.**
4. **NEGLIGENCE – FAILURE TO WARN**
5. **NEGLIGENCE – FAILURE TO TEST**
6. **STRICT PRODUCT LIABILITY**

DEMAND FOR JURY TRIAL

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Plaintiffs Heather Wanke, Mia Jones and Janice Newman (collectively, "Plaintiffs"), through counsel, file this Original Complaint against Defendant Invasix Inc. ("Invasix" or "Defendant") and respectfully state as follows:

NATURE OF THE ACTION

1. Plaintiffs seek redress for permanent facial disfigurement and personal injury caused by the Fractora procedure, a radio frequency-based cosmetic surgery performed with a Fractora device (the "Product") designed, manufactured and sold in North America by Invasix.

JURISDICTION AND VENUE

2. The Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(a) because this is a lawsuit in which over $75,000 is at issue and Plaintiffs are citizens of states other than Defendant's state of citizenship. The Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events giving rise to the claims asserted occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendant conducts substantial business in this District, has sufficient minimum contacts with this District, and otherwise purposely avails itself of the markets in this District, through the promotion, sale, and marketing of the Product in this District.

PARTIES

4. Plaintiff Heather Wanke is a citizen of Tennessee, residing in Murfeesburo, Tennessee.

5. Plaintiff Mia Jones is a citizen of Tennessee, residing in Murfeesburo, Tennessee.

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6. Plaintiff Janice Newman is a citizen of New York, residing in Floral Park, New York.

7. Defendant Invasix Inc. is a corporation formed under the laws of Delaware, with its principal North American office in Ontario, Canada. Defendant Invasix, Inc. may be served through its registered agent, C.T. Corporation System, 818 West Seventh St. 2nd Floor, Los Angeles, CA 90017.

FACTUAL BACKGROUND

8. Defendant designed, manufactured, marketed, sold and distributed the Product throughout the United States at all times relevant to this Complaint.

Product Received 510(k) FDA Clearance

9. Under the Food, Drug and Cosmetic Act of 1938, as modified by the Medical Device Amendments of 1976 (the "FDCA"), the U.S. Food and Drug Administration ("FDA") has authority to regulate medical devices. If a device "support[s] or sustain[s] human life" or "presents a potential unreasonable risk of illness or injury," it is designated a "Class III" device for which pre-market approval by the FDA is required. 21 U.S.C. § 360c(a)(1)(C)(ii). The FDCA presumes all devices are Class III devices unless a manufacturer demonstrates otherwise. To obtain pre-market approval, a device manufacturer typically must show the "safety and effectiveness [of the device] under the conditions of use set forth on the label." § 360c(a)(2)(B).

10. However, a device may also be cleared for sale by the manufacturer if found by the FDA to be substantially equivalent to a "predicate" device that was legally marketed prior to May 28, 1976. 21 CFR § 807.92(a)(3). To obtain FDA-clearance under the substantially equivalent standard, a procedure commonly referred to as 510(k) clearance and the least stringent of all processes for FDA-approval of a medical device, a manufacturer must submit, among other things, a statement of intended use and proposed labeling and instructions for use of the device. "Section 510(k) clearance is not

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equivalent to FDA 'approval' of a device. Instead, the FDA only clears such devices for the limited uses identified by the manufacturer in the § 510(k) application." *U.S. v. Medtronics, Inc.*, 2017 US DIST. LEXIS 153887, at *6 (CD Cal. Sept. 11, 2017) (citing 21 CFR § 807.97 and 801.5)).

11. A manufacturer must submit a new 510(k) application or seek pre-market approval if there is any "change or modification in the device that could significantly affect the safety or effectiveness of the device" or "major change or modification in the intended use of the device." 21 CFR 807.81(a)(3).

12. Defendant obtained 510(k) clearance of the Product.[1]

13. Since the Product received its 510(k) clearance, the FDA announced its plan to overhaul this relatively lax procedure, acknowledging that the 510(k) clearance "framework needs to be modernized to reflect advances in technology, safety and the capabilities of a new generation of medical devices."[2] As is discussed in more detail below, Defendant markets the Product as just such a revolution in medical devices, claiming it is a safer alternative to more traditional, ablative and invasive procedures.

[1] Brian Lodwig, President of Invasix, confirmed that the 510(k) FDA clearance application for the product included the February 2011 Operator's Manual. Invasix submitted that application, Fractora K102461, on or about March 25, 2011.

[2] Statement of FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, Nov. 26, 2018, at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm. CNBC associates the FDA's announcement with "scathing investigations into medical device failures and how the FDA's accelerated review process may have missed problems and put consumers at risk." Angelica LaVito, CNBC, FDA to Overhaul More than 40-Year old Process for Approving Medical Devices that Some Say Puts Consumers at Risk, November 26, 2018, at https://www.cnbc.com/2018/11/26/fda-to-overhaul-510k-medical-device-approval-process.html.

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14. According to documents submitted by Defendant to the FDA as part of the 510(k) clearance process, the Product is "composed of a console, hand held applicator, and disposable tip, designed to deliver bipolar radiofrequency electrical current to the skin surface, via an array of multi-electrode pins." The Product is intended for "dermatological procedures requiring ablation and resurfacing of the skin."

15. More specifically, the Fractora procedure performed by the Product uses radio frequency energy to selectively vaporize columns of skin while leaving adjacent skin relatively uninjured. The intentional injury stimulates the body's production of collagen, which leaves the skin looking and feeling smoother. Because adjacent skin theoretically remains relatively uninjured, Defendant claims the Fractora procedure is safer and requires less recovery time than alternative procedures such as those performed with other ablative devices, such as scalpels, lasers and chemicals.

Defendant's Failure to Disclose the Financial Interest of Doctors Recruited to Assist in Sales

16. Defendant sells the Product to doctors. In order to promote sales, Defendant recruits well known and/or well-regarded doctors, doctors it considers to be opinion leaders, to use and promote the Product through what Defendant refers to as the Luminary Program. Luminary Program members conduct trainings and demonstrations to prospective doctor-customers and the media, prepare white papers, conduct so-called studies, provide testimonials and create referrals in exchange for honoraria, extended training, product discounts, compensation for referrals and other perks.

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17. However, Defendant does not disclose its connection to the Luminary Program doctors, that the doctors have been compensated for their participation or that the trainings, demonstrations, "studies," white papers and testimonials constitute no more than promotional materials.[3] Instead, Defendant present these materials as though they are independent and, in the case of purported studies and papers, the result of objective scientific study, which they are not.[4]

18. Defendant relies heavily on one opinion leader in particular, Dr. Stephen R. Mulholland, a plastic surgeon with a private aesthetics practice in Toronto, Canada. Mulholland co-invented the Fractora technology and co-founded Invasix. He continues to own roughly 17% of the company.

[3] According to the FDA, any statement by a manufacturer to a third party is a promotional activity, including, but not limited to statements made by sales representatives to doctors or patients, statements made in marketing materials, such as web and social media sites, sales brochures, direct-to-consumer advertising, as well as statements made in press releases, training materials, or by way of depictions and demonstrations. Use of health care providers to "train" on a product is also promotional, particularly if the health care provider is chosen by the company and receives compensation of any form for his or her assistance. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, published by the FDA in December 1997, which is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf.

[4] The President of Invasix has confirmed the existence of the Luminary Program and the company's compensation of its members in exchange for Luminary duties. However, specifics concerning the Luminary Program members—such as the identity of its members, the compensation or other financial incentives provided by Defendant in exchange for Luminary duties, and when and in what form (i.e., demonstrations, so-called studies, white papers, etc.) the Luminaries have made statements about the Product in Invasix-sponsored activities— is exclusively within the knowledge of Defendant and the information unavailable to Plaintiffs prior to discovery. An example of Luminary video and written testimonials, demonstrations and white papers can be found on Defendant's website at inmodemd.com.

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19. Invasix clearly sponsors the Dr. Mulholland demonstrations: Invasix employees extend invitations and provide materials. Yet, rather than disclose the financial interest of both Invasix and its owner, Dr. Mulholland, the presentation aides and materials mention nothing of Dr. Mulholland's ties to Invasix and the Fractora technology, implying that Dr. Mulholland is no more than an independent practitioner besotted with the Fractora procedure.[5]

20. The FDCA and California consumer protection statutes and common law prohibit this type of deception in the sale of medical devices. *See* 21 USC §§ 331(b) and 352(f). FDA regulation also requires reporting of annual payments to those conducting research regarding a medical device, like Dr. Mulholland and many of the Luminary Program members, exceeding $25,000 a year or equity stakes in public companies worth more than $50,000 and any equity stake in private companies, such as Invasix. *See* 21 C.F.R. §§ 54.2(f) & 54.4 (1999) and 42 C.F.R. § 50.603.[6] At a minimum, Invasix's

[5] Defendant makes these misrepresentations and omissions concerning Dr. Mulholland and his connection to Defendant in, among other things, a PowerPoint presentation and white papers used by Defendant and Dr. Mulholland at the demonstrations. Because Defendant believes the PowerPoint document to be proprietary and confidential, Plaintiffs do not attach it as an exhibit; however, Plaintiff provided Defendant a copy prior to filing this Complaint (and in Defendant's possession prior to that time as well). A slide introducing Dr. Mulholland refers only to his private aesthetics plastic surgery practice. A slide introducing Invasix lists company "founders," but fails to identify Dr. Mulholland among them. The presentation also includes white papers authored by Dr. Mulholland but in which his connection to Defendant goes undisclosed. Dr. Mulholland's curriculum vitae lists the dates and locations of his many Fractora demonstrations. Because Defendant views the document as proprietary and confidential, and because it is voluminous, Plaintiffs do not attach it as an exhibit.

[6] *See also* FDA Guidance for Clinical Investigators, Industry and FDA Staff: Financial Disclosure by Clinical Investigator, pt. IV.A.2 (2013), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf. The Public Health Service has similar requirements; under its regulation, a clinical investigator like Dr. Mulholland must disclose an equity interest in

failure to disclose Dr. Mulholland's connection to the company violates the FDCA and its implementing regulation.

Defendant Impermissibly Endorses False, Misleading and Fraudulent Promotion of Product and Fails to Disclose Increased Risk of Unintended Injury

21. Use of these types of opinion leaders is a powerful marketing tool and Invasix spends a great deal of time, money and effort to utilize these leaders. A growing body of empirical evidence suggests that even seemingly trivial perks, such as pens and specialty promotional items, can exert undue influence.[7] Of course, Defendant offers its Luminaries much more than trinkets.

22. Doctors subject to these kinds of manipulations are often blinded to the objectively verifiable bias,[8] including members of Defendant's Luminary

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excess of $5,000 in a public company and any ownership interest in a privately held business. 21 C.F.R. § 54.2(b).

[7] *See, e.g.*, Deborah Korenstein, Salomeh Keyhani & Joseph S. Ross, *Physician Attitudes Toward Industry: A View Across the Specialties*, 145 ARCHIVES SURGERY 570, 573, 577 (2010); *see also* ASS'N OF AM.MED. COLLS., THE SCIENTIFIC BASIS OF INFLUENCE AND RECIPROCITY: A SYMPOSIUM 1 (2007) (discussing a "growing body of a neurobiological and psychosocial evidence related to the effects of gifts on recipients' choices and decisions"); *see also* L. Lewis Wall & Douglas Brown, *The High Cost of Free Lunch*, 110 OBSTETRICS & GYNECOLOGY 169, 171 (2007) (noting that "[t]he provision of food is an especially powerful tool in shaping perceptions and increasing the sense of reciprocal obligation in cultures around the world"); Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, July 28, 2006, at A1 (reporting that some physicians' offices receive breakfast and lunch paid for by pharmaceutical companies every day and that the companies spend hundreds of millions of dollars each year on such meals); Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 253 (2003).

[8] *See, e.g.*, Ann H. Harvey, Ulrich Kirk, George H. Denfield & P. Read Montague, *Monetary Favors and Their Influence on Neural Responses and Revealed Preference*, 30 J. NEUROSCIENCE 9597, 9600–01 (2010) (reporting on research

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Program. Luminaries exaggerate the benefits of the Product by using it in a way significantly more aggressive than proposed by Defendant in its 510(k) submissions to the FDA. This allows for more dramatic results. It also dramatically increases the risk of unintended injury to the patient. Yet Luminary Program members downplay potential risks, such as burning, scarring and nerve damage, and tout the Product as safer than alternative procedures.

23. Like the so-called studies, white papers, live demonstrations, videos and other resources created by Luminary Program members, Dr. Mulholland employs the Product device using much more aggressive parameters and techniques than the FDA-cleared use instructions/warnings. And like the Luminary Program members, Dr. Mulholland fails to warn new and potential doctor-customers that the device parameters and techniques he is using are not FDA-cleared and substantially increase the risks of unintended injury to patients.

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demonstrating that "[a] monetary favor from a company was indeed capable of robustly influencing preference for art paired with the logo of the sponsoring company logo. . . . despite the fact that subjects were unfamiliar with the company logos, subjects had no reciprocal interaction with the company, and the only association between the art and the sponsoring company was visual juxtaposition on a computer screen," and despite the fact that the subjects of the research did not believe "the presence of the logo influenced their ability to judge the paintings"); *see also* Azgad Gold & Paul S. Appelbaum, *Unconscious Conflict of Interest: A Jewish Perspective*, 37 J. MED. ETHICS 402, 404 (2011) ("It seems that the Talmudic answer to this question is clear. On the psychological level, one cannot escape the deleterious unconscious effects of receiving a gift. As a human being, the recipient is biased, no matter how wise and otherwise reasonable the person may be."); Don A. Moore, Philip E. Tetlock, Lloyd Tanlu & Max H. Bazerman, *Conflicts of Interest and the Case of Auditor Independence: Moral Seduction and Strategic Issue Cycling*, 31 ACAD. MGMT. REV. 1, 2 (2006) (arguing that, with specific regard to auditors, "[p]utting the most Machiavellian fringes of professional communities aside, . . . the majority of professionals are unaware of the gradual accumulation of pressures on them to slant their conclusions—a process we characterize as moral seduction").

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24. More particularly, the purported studies, white papers, live demonstrations, videos and other resources created by Luminary Program members, Dr. Mulholland included, employ the following aggressive device parameters and user techniques, all of which are at odds with Invasix's 510(k) FDA application for the Product:

(a) Failure to use the lowest energy output setting necessary to achieve the desired surgical effect, instead typically promoting the use of the Product at or near the highest energy levels (i.e., 20-30 mJ/pin versus 40-62 mJ/pin, 62 mJ/pin being the highest setting);

(b) Failure to reduce Product energy output setting over bony areas, such as the cheek bones and forehead, and further reduce the settings over areas of thin skin, such as the neck and under the eyes;

(c) Use of unreasonable number and configuration of multi-electrode pins (i.e., the 24 versus 60 or 126 pin tip);

(d) Unreasonable length of multi-electrode pins (i.e., 3000 micron versus 600 micron);

(e) Use of unreasonable lack of coating (versus coated) on multi-electrode pins;

(f) Failure to use the output setting for the shortest amount of time necessary to achieve the desired surgical effect, (i.e., use of unreasonable number of passes with Product over the same area of the body);

(g) Use of unreasonable amount of pressure with which the handpiece is applied to the patient's skin; and

(h) Failure to overlap the applicator tip by 30-50%, thereby causing an overlap of one negative electrode on top of another, resulting in too much superficial positive current flowing up to the negative electrode in that area.

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25. By way of example, in the Power Point presentation used by Dr. Mullholland at his demonstrations, a "Typical Parameters for Clinical Effects" slide encourages use of the Product at energy levels significantly higher than those presented to the FDA and with no reference to pin tip, reduction in energy for bony areas or areas of thin skin, or any warning that usage at higher energy levels increases the risk of burns, scarring and nerve damage. The presentation also includes slides depicting Fractora treatment results using the machine at the very highest energy settings, including on the neck and under the eyes, in contradiction to FDA cleared parameters.

26. The white papers and testimonials also illustrate these misrepresentations and omissions. These white papers summarize small, so-called clinical studies of the Fractora procedure using the device at energy settings of 60 mJ/pin—nearly the highest available setting—for the face and neck. This setting is significantly higher than those in the FDA clearance application materials, particularly in areas in which the FDA clearance materials require a twenty percent reduction in energy setting for bony areas, such as around the eyes, and another twenty percent reduction in areas of thin skin, such as the forehead and neck. The white papers also include before and after photo depictions of the patient subjects, indicating dramatic results in just one treatment using these aggressive parameters.

27. Since the statements made by Dr. Mulholland and Luminaries are promotional, they are imputed to Invasix even though Invasix does not directly employ the doctors. The FDA considers off-label promotion by a device manufacturer, whether express or implied, to be a violation of the FDCA, particularly 21 USC §§ 331(b) and 352(f). *See also Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815(9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA."); *Schouest v. Medtronic,*

Inc., 13 F. Supp. 3d 692, 703-706 (S.D. Tex. Mar. 24, 2014) (same).

28. Off-label use encompasses use of techniques and device parameters that vary from the FDA approved instructions/warnings. *See, e.g., Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1209-1210 (N.D. Cal. May 13, 2014) (noting that the FDA's approval letter for the device required implantation from the anterior (front) abdomen using an LT Cage and finding "Any operation that uses the Device in a manner other than that approved by the FDA is called an "off-label" use. This includes operations in which the spine is approached from the back and operation without the LT Cage.")*.* Similarly, it includes use of the device at odds with prohibitions found in the FDA cleared instructions/warnings, such as the requirement of a prescription, limiting use to within a hospital or clinic facility or, as in the case of the Product, limiting use to licensed physicians. *See Coyne Beahm, Inc. v. United States FDA*, 966 F. Supp. 1374, n. 27 (M.D.N.C. 1997) (citing legislative history, H.R. 94-853 at 24-25 (1976)).

29. Since Dr. Mulholland and the Luminary Program members endorse use of the Product in a way contrary to the FDA-cleared instructions/warnings for use, and because these endorsements are imputed to Invasix, the demonstrations and promotional materials offered by Dr. Mulholland and the Luminary Program members constitute off-label promotion of the Product by a manufacturer in violation of the FDCA.

30. Moreover, because these promotional demonstrations and materials omit critical warnings about likely risks, they are also false, fraudulent and misleading and in violation of California consumer protection laws and the FDCA. More specifically, the opinion leaders used by Invasix to promote the Fractora device fail to inform their audience that (1) use of the device at a higher energy level increases the risk of burns, scarring and nerve damage, (2) energy settings should be reduced on bony areas and areas of thin

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skin, such as forehead and cheeks, and (3) users, like Plaintiffs' doctors, could achieve the same results by using less energy over multiple sessions, thereby reducing the risk of injury.

31. Invasix makes the so-called studies, white papers, videos and other resources created by Luminaries and other health care professionals financially interested in the sale of the device available to prospective and new buyers/users through its website, inmodemd.com, and an electronic portal, access to which is given to new and potential owners/users by email. Defendant reviews these materials, particularly those involving Dr. Mulholland, with new and prospective doctor-customers during in-office demonstrations and trainings. In other words, Defendant indoctrinates all new and prospective Product owners with these false, fraudulent and misleading materials.

False, Misleading and Fraudulent Promotion of Product and Product Defect—Inconsistent and Inadequate Product Labeling

32. Invasix's Product labeling is equally flawed.[9] A device is "defective" if its instructions fail to provide those who can prescribe the device with all the necessary information (approved by the FDA) to use their medical expertise in deciding whether to prescribe the drug or device. Where this information is inadequate or incomplete, the company may be liable under theories of strict product liability (failure to warn), product liability (failure to warn) and negligence (failure to act as a reasonable product device manufacture by way of inadequate or poor warnings).

33. Since receiving 510(k) FDA-clearance in 2011, Invasix has issued users new Product operator manuals and Clinical Bulletins with grossly inconsistent and inadequate instructions/warnings regarding permissible energy

[9] The FDCA defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying any such article." *See* 21 U.S.C. § 325(a).

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settings, selection of the appropriate disposable tips and multi-electrode pins and procedure techniques, such as the permissible amount of overlap and pressure with which to apply the hand held applicator tip. Similarly, the Product manuals and Clinical Bulletins fail to adequately warn users of known risks associated with the Product, including, but not limited to, the risk of long term nerve damage.

34. Details specific to each Plaintiff and their respective health care providers follow.

False, Misleading and Fraudulent Promotion of Product and Product Defect—Promoting Use of Product by Non-Physicians

35. The Product is a prescriptive device that may only be used upon a physician's order. The FDA-cleared Product Operator Manual and all subsequent manuals further restrict use of the Product to licensed physicians. Nevertheless, Invasix regularly markets the Product to doctors for use by non-physicians, encouraging existing and prospective buyers to increase their rate of return by delegating Fractora procedures to nurses and, in some cases, estheticians, who have no or little medical training. Invasix trains these non-physicians on Product usage in direct contradiction to warnings and restrictions included in the FDA-cleared product manual.

36. Defendant's practice of promoting use of the Product by non-Physicians violates the FDCA as impermissible off-label promotion, renders the Product defective under applicable product liability law, constitutes breach of express and implied warranties and amounts to negligence and negligence per se.

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False, Misleading and Fraudulent Promotion of Product—Failure to Report Adverse Events

37. The FDA and California consumer protection laws require manufacturers like Invasix to report adverse events related to use of its medical devices. This requirement is key to the FDA's role in patient safety. If manufacturers fail to comply, the FDA cannot protect unsuspecting patients from unsafe medical devices or procedures made unsafe by a manufacturer's false, misleading or fraudulent promotion of a medical device.

38. The Medical Device reporting regulation, 21 C.F.R. 80350(a), requires manufacturers to report device-related adverse events within thirty (30) days of "receiving or otherwise becoming aware of information, from any source, that reasonably suggest that the device it markets" *may* have caused or contributed to a death or serious injury. FDA guidance makes clear, adverse event includes any undesirable experience, certainly including permanent impairment to a body structure or when additional treatment was necessary to prevent such impairment. *See* FDA guidance, available at https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm.

39. The reporting requirement applies equally to situations where the adverse event was or may have been the result of a device malfunction, a device defect or user error. *See* FDA Guidance for Industry and Food and Drug Administration Staff, Medical Device Reporting for Manufacturers, published in 2016, available at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf.

40. Invasix has unlawfully suppressed reporting of adverse events that may have prevented injury to Plaintiffs. Plaintiffs are aware of at least *eleven* victims of the Fractora procedure—all of whom Invasix is aware—that fall within the mandatory reporting guidelines. In some cases, the President of

Invasix has himself referred to the incidents as "adverse events." Yet, Invasix has yet to report a single adverse event related to the Fractora procedure. In so doing, Invasix violated the FDCA and failed to follow its own internal Risk Estimation and Evaluation of Customer Complaint guide.

41. Invasix further suppresses FDA adverse event reporting by its practice of downplaying the seriousness of injuries suffered by Fractora patients when contacted by concerned physicians. This practice emanates from those in positions of highest authority within Invasix and is, thus, corporate-driven and wide scale interference with the very FDA regulation meant to protect unsuspecting consumers.

42. Defendant's practice of suppressing adverse event reporting is a form of impermissible off-label promotion under the FDCA and California consumer protection laws; it also renders the Product defective under applicable product liability law, constitutes breach of express and implied warranties and amounts to negligence and negligence per se.

FACTS RELATING TO PLAINTIFFS

Plaintiff Heather Wanke

43. Prior to the Fractora procedure performed by Dr. Paulino E. Goco, located in Nashville, Tennessee, on June 15, 2017, Heather was a young-looking forty-three (43) year old dietician. She and her husband lived an active and social life in Nashville. Heather sought treatment only to refresh her skin, which was virtually wrinkle-free with small pores and a healthy-looking olive complexion.

44. Dr. Goco recommended the Fractora procedure, claiming it was a very safe, cutting edge, painless and non-invasive alternative to face lift and other energy based (laser) procedures. He also assured Heather the procedure was risk-free and would require little downtime. He failed to inform her that the procedure rarely requires the general anesthesia he recommended for her

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treatment or that he intended to use extremely aggressive treatment parameters for the procedure despite Heather's nearly perfect skin condition.

45. Far from safe, the Fractora procedure left Heather with severe, claw-like scarring on her right cheek, ice pick-like scarring to her entire face and changes to the texture of her skin, leaving her with an orange peel look. These scars persist despite over a year of healing and one additional, painful Fractora procedure intended to improve the scarring.

46. Dr. Goco placed Heather under general anesthesia for her treatment on June 15, 2017. According to a Clinical Bulletin published at or around the same time as the 2011 Operator's Manual for which Invasix received FDA clearance of the Fractora device, users select three parameters: tip size, energy per pin (10-62 mj) and treatment mode (single or multiples pulses). Dr. Goco selected nearly the most aggressive of the tip size and treatment mode parameters for treatment on Heather's entire face and the highest energy settings for areas in which the energy levels should have been reduced, such as on Heather's sensitive eye and cheek areas.

47. More particularly, Dr. Goco used the 24 pin tip, with the 3000 micron presumably uncoated tips at two pulses, "double stacked" for two passes over Heather's entire face. He administered the tissue destroying radio frequency at 25 mj for Heather's forehead, brow and lower eye lid areas, at 50 and 45 on her cheeks and around her mouth and at 45 for between her brow, crow's feet area and perioral. In all, Dr. Goco dispensed more than 1,400 pulses on Heather's face.

48. Invasix had not provided Dr. Goco an updated Quick Reference Guide ("QRG") at the time of the procedure although it created a new QRG in March 2017. So, Dr. Goco referred to the only QRG provided to him at the time of the procedure: the January 2015 QRG. A comparison of the two guides reveals the January 2015 instructions to be much more aggressive than

Invasix actually believed safe at the time. For the treatment of wrinkles, the January 2015 QRG directs doctors to use the 24 pin 3000 micron uncoated tips at the highest energy settings available on the machine, 40-62 mj, on soft tissue. The March 2017 QRG, on the other hand, recommend use of only 25-50 mj. (The March 2017 QRG also suggests use of the coated pin tip for people like Heather with skin type IV.)

49. When another patient suffered similar injuries later that year, Dr. Goco wondered in an email, "why did they not give us a notice [that the treatment instructions had changed] and update training information???"

50. These outdated and unsafe instructions, closely followed by Dr. Goco, were all the more dangerous because, as a May 2014 Invasix Clinical Bulletin points out, the 24 pin tip delivers heat deeper than any of the other Fractora pin tips and because of the doctor's selection of multiple pulses and passes. All of these parameters are in excess of those included in FDA-reviewed 2011 Operator's Manual. In particular, the Operators Manual warns:

> Use the lowest output setting necessary to achieve the desired surgical effect. Use of the RF energy only for the minimum time necessary in order to lessen the possibility of unintended burn injury. The higher the RF energy and the longer the RF energy is applied, the greater the possibility of unintended thermal damage to tissue …

51. Worse still, Dr. Goco employed a dangerous technique on both passes of the Fractora. Rather than overlapping the hand piece, Dr. Goco "double stacked." That is, he applied one of the highest energy levels using a pin tip delivering heat deeper than the alternatives, twice to the same area without overlap. Dr. R. Stephen Mulholland, the co-founder of Invasix and co-inventor of InMode/Fractora, wrote in 2015 that the Fractora handpiece should be applied with overlap of "approximately 30-50%, with care taken not to overlap one negative electrode on top of another." He warned that failure to overlap will result in unintended thermal damage.

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52. Dr. David Goldberg, hired by Invasix to speak and train on its InMode device and widely renowned as among the best cosmetic dermatologists and energy-based device doctors, shares Dr. Mulholland's belief that a failure to overlap the Invasix tip will lead to injuries such as those suffered by Heather. Likewise, Invasix Fractora Quick Reference Guides dated January 2013 (recommending approximately 20% overlap), December 2013 (same), January 2014 (recommending approximately 30-50% overlap), January 2015 (same) and May 2015 (same) echo Dr. Mulholland's instructions to use overlap.

53. Nevertheless, the 2011 Operator's Manual (page 25) instructs physicians to use minimal overlapping, suggesting that overlap should be avoided.[10] A Clinical Bulletin issued at approximately the same time also instructs physicians not to overlap.

54. But Invasix has since issued multiple other "labeling documents" (as that phrase is defined by the FDA) with inconsistent instructions/warnings as to overlap. The most notable of these documents is the May 2014 Clinical Bulletin, presumably relied upon by Dr. Goco, in which, contrary to the peer-reviewed writing of Dr. Mulholland, Invasix told physicians, "Stacking pulses in the same site may improve the results . . . . It is safe to stack with the 24 pin tip, as the heat is deeper but be more careful with the non-coated tips." In the Bulletin, Invasix acknowledged, "Stacking may increase the risk of side-effects. Therefore, . . . On boney (sic) areas . . . treat with reduced energy, and gradually increase energy **to a maximum of 25mJ/pin**. Avoid using 24 pin tip if response of test pulse is excessive." (Emphasis added.)

55. Dr. Goco told Heather to expect less than five days downtime so

[10] Invasix failed to update that manual until December 2015; nor has it submitted the 2015 manual for FDA clearance. The 2011 Operator's Manual remains the only FDA cleared instructions/warnings for the device.

Heather knew something had gone terribly wrong when she remained swollen with puncture mark wounds all over her face at day 3 and 4 of her recovery. She remained housebound at day 7. Her skin looked even worse beginning at day 10—as the swelling subsided, Heather's smooth, clear skin came to look and feel like orange peel, the skin under her eyes darkened and burns left claw and moon shaped scaring on her cheeks, upper lip and chin and between her brow.

56. Dr. Goco shared Heather's concern, requiring multiple follow up appointments. In notes from July 12, 2017, Dr. Goco noted "hyperpigmentation." He repeated a VISIA Facial Assessment Report on Heather that same day. As compared to an assessment taken June 9, 2017, just before the Fractora procedure, Heather's skin scored 60-90% worse in assessments including "spots," "wrinkles," "texture" and "pores."

57. Heather cried and cried in Dr. Goco's treatment room. Neither the doctor nor his staff could console her. Dr. Goco became so alarmed at Heather's distress, he left a personal voice mail message for her after the July 12, 2017 appointment. In it, Dr. Goco acknowledged that Heather would need multiple additional treatments to address the injuries sustained as a result of the Fractora treatment.

58. In a third follow up appointment on July 28, 2017, Dr. Goco identified the injuries as "ice-pi[c]k type dimple scars," "deeper around chin and brow." He instructed Heather to continue wound care and offered her a (completely unsolicited) refund for the procedure.

59. In September 2017, Heather saw Dr. Natalie Curcio for restorative treatment. Dr. Curcio noted extensive scarring, which she attributed to "a prior laser resurfacing that was too aggressive." Dr. Curcio encouraged Heather to undergo a second Fractora procedure. The procedure caused Heather extreme anxiety as a result of her prior bad experience. It did little to improve her scars

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and discoloration.

60. While Heather should pursue further improvement through additional restorative treatments, these procedures are expensive, painful and risky. They also take an emotional toll. And no amount of additional treatment will completely reverse the scarring and hyperpigmentation marking Heather's face.

61. Heather's damages also include lost wages. Heather missed no fewer than fifty-nine (59) from work as a nutritionist—approximately thirty (30) days immediately following the procedure, another roughly twenty (20) days in the month of August, when Heather researched her condition and possible cures obsessively, and another nine (9) days for the second, restorative Fractora procedure. Heather's daily rate of pay is $240/day, making her damages for lost wages at the time of filing $14,160.

62. In addition, Heather has operated a virtual health and dietary supplement franchise, YOY, since 2012. Her business, like the health and wellness industry as a whole, grew exponentially between 2012 and 2016. In 2018, Forbes described growth in the health and wellness industry generally as a "boom," particularly since 2015-2016. *See* https://www.forbes.com/sites/forbeslacouncil/2018/04/27/what-businesses-can-learn-from-the-health-and-wellness-boom/#490ad789341e. In fact, YOY enjoyed its largest increase in her revenue in 2016, despite Heather's inability to promote the business for approximately nine (9) months due to family obligations. Had Heather been actively working on YOY that year, we can conservatively estimate her growth would have been more than double her actual numbers, or a total increase of more than $26,000.

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63. We would have expected YOY to increase by more than that amount in 2017 and 2018 but for the injuries Heather sustained as a result of the Fractora, when, instead, her sales became stagnant. Heather's lost profits for YOY because of the Fractora total more than $56,000, assuming only that she would have matched her growth for 2016.

64. Heather also incurred $4,005.10 in out of pocket expenses for medications, ointments and other costs of treatment.

65. Thus, Heather's economic damages alone exceed $75,000.00.

66. Heather has suffered emotionally, too. She is a young, beautiful woman who, until her permanent scarring, enjoyed the good fortune of healthy, young looking and virtually wrinkle and damage-free skin. The changes in Heather's face cause her to appear older and less healthy. The scars around her mouth actually look like smoker's lines. This is particularly hard for Heather, who makes her living in the wellness and health industry. She is inconsolable at the prospect of a lifetime of facial scars.

67. As a result of her disfigurement, Heather has experienced extreme anxiety, depression, sleeplessness, loss of appetite, irritability and, worst of all, a significant decrease in her self-esteem. Her lack of confidence has in many ways changed the dynamics of daily life. She has retreated from what had been a very active and happy social life: she stopped attending church; business networking events; Pure Barre, her favorite exercise activity; coffee dates; girls' nights; couples' events; and dates with her husband. She missed her twenty-fifth high school reunion and her college homecoming game and accompanying celebrations. She has declined public speaking engagements, which she previously accepted and enjoyed. Her anxiety about being seen publicly became overwhelming, turned Heather into a recluse. Friends began to worry and inquire about her nearly total absence from their usual bustling social scene.

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Plaintiff Janice Newman

68. Plaintiff Janice Newman is a forty-seven year-old woman who resides in Floral Park, New York. She is a public figure, working as a broadcaster for twenty-five years, fourteen of them as a television meteorologist. Most recently, Janice appears on Fox & Friends, a daily news and talk program that airs weekdays nationally on the Fox News Channel between 6:00 a.m.- 9:00 a.m. In addition, Janice appears on the Fox Business Network, various radio programs and as a substitute for Fox News Live headline anchors. Janice began her work with Fox News in 2003; before that, she appeared on several radio and television stations in Canada and in the United States, including Imus in the Morning, CHEZ-FM and WCBS-TV.

69. Janice is married to Sean Newman of the New York City Fire Department. Together, she and her husband have two young sons, ages eight and six.

70. Janice is young and extremely active. Her only issue was a few wrinkles on her neck. She agreed to undergo a Fractora procedure performed by Dr. Jon B. Turk on February 16, 2017 based on her doctor's recommendation and claims made by Invasix in brochures, posters and in the media that it is a safe, less invasive alternative to surgical and other energy-based procedures and that she could expect to heal much more quickly than if undergoing comparable procedures.

71. Far from safe, the Fractora procedure left Janice with severe—and, to date, permanent— nerve damage, causing continuing facial paralysis, drooping and an uneven smile. For months, Janice suffered symptoms so severe, she could not speak clearly and had difficulty eating and drinking. Even now her smile, which is critical to her role as a television broadcaster and public media figure among other things, remains asymmetrical. In addition to the severe nerve damage, she also suffered permanent scarring on her neck.

72. Dr. Turk placed Janice under general anesthesia for her treatments on February 16, 2017. He began with another Invasix treatment, FaceTite, applied to Janice neck. He followed the FaceTite immediately with the Fractora procedure. Dr. Turk selected nearly the most aggressive of the parameters available for the Product for both of two passes performed on Janice's sensitive neck area.

73. For the first pass, Dr. Turk used the 24 pin coated tip at 55 mJ/pin with two pulses. As a May 2014 Invasix Clinical Bulletin points out, the 24 pin tip delivers heat deeper than any of the other Fractora pin tips.[11] Similarly, the 55 mJ/pin energy setting is just shy of the device's very highest setting of 62 mJ/pin and particularly aggressive given the doctor's selection of multiple pulses. All of these parameters are in excess of those included in FDA-reviewed 2011 Operator's Manual. In particular, the Operator's Manual warns, "Use the lowest output setting necessary to achieve the desired surgical effect. Use of the RF energy only for the minimum time necessary in order to lessen the possibility of unintended burn injury. The higher the RF energy and the longer the RF energy is applied, the greater the possibility of unintended thermal damage to tissue . . . ." For treatment of lax skin on Fitzgerald Skin Types I-III, which applied to Janice, the May 2015 Quick Reference Guide instructs physicians to use the 24-coated pin tip at no more than 30-40 mJ/pin on soft tissue and 20-30 mJ/pin when working on bony areas.

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[11] Prior to discovery, Janice cannot be sure what materials Invasix had provided to Dr. Turk at the time of her procedure; that information is known to Defendant. Based on representations made about Dr. Turk's experience with the procedure, Janice believes he received all of the materials cited in the section of this Complaint detailing her procedure and injuries.

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74. Worse still, Dr. Turk employed a dangerous technique on his first pass of the Fractora. Rather than overlapping the handpiece, Dr. Turk "triple stacke[d]." That is, he applied one of the highest energy levels using a pin tip delivering heat deeper than the alternatives, not just once or twice, but three times to the same area without overlap.

75. Again, Invasix has provided Product users inconsistent instructions with regard to use of overlapping. Both the 2011 and updated 2014 Operator Manuals instruct physicians to use minimal overlapping, suggesting that overlap should be avoided. A Clinical Bulletin issued at approximately the same time also instructs physicians not to overlap.

76. But Invasix has since issued multiple other "labeling documents" (as that phrase is defined by the FDA) with inconsistent instructions/warnings as to overlap. The most notable of these documents is the May 2014 Clinical Bulletin, presumably relied upon by Dr. Turk, in which, contrary to the peer-reviewed writing of Dr. Mulholland, Invasix told physicians, "Stacking pulses in the same site may improve the results . . . . It is safe to stack with the 24 pin tip, as the heat is deeper but be more careful with the non-coated tips." In the Bulletin, Invasix acknowledged, "Stacking may increase the risk of side-effects. Therefore, . . . On boney (sic) areas . . . treat with reduced energy, and gradually increase energy **to a maximum of 25mJ/pin**. Avoid using 24 pin tip if response of test pulse is excessive." *Id.* (emphasis added).

77. Dr. Mulholland warned in 2015 that failure to use approximately 30-50% overlap would result in unintended thermal damage. This risk includes the nerve damage Janice has suffered; nevertheless, Invasix has utterly failed to warn doctors and patients of the risk of prolonged facial paralysis due to nerve injury—not in its Operator Manuals, Clinical Bulletins or elsewhere.

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78. Dr. Turk followed up with a second pass of Janice's "central neck," selecting a 50 mJ/pin energy level but using the 60 pin tip with a single pulse. Here again, Dr. Turk selected much too aggressive parameters. According to the May 2015 Quick Reference Guide, when treating even deep wrinkles, the 60 pin tip should be used at no more than 30-45 mj on bony areas, which should be reduced by 20% when working on areas of thin skin, such as the neck.

79. For months, Janice suffered symptoms so severe, she could not speak clearly and had difficulty eating and drinking. Even now her smile, which is critical to her role as a television broadcaster and public media figure among other things, remains asymmetrical. In addition to the severe nerve damage, she also suffered permanent scarring on her neck.

80. Janice noticed a problem right away. The morning after the procedure, she wrote Dr. Turk's office manager to ask "if it's normal that one side of my face is more swollen than the other? It's a little challenging to talk out of the side of my mouth that's swollen." Later that day, she explained, "my face is a bit droopy and I'm lisping a bit when I talk and my smile is off center." A few days later, February 20, 2017, she wrote, "Still [a] little worried about the swelling and the left side of my mouth. I have this weird lopsided smile!"

81. By March 1, 2017, Janice had attempted to return to work. She finished one segment before Fox News producers pulled her off the air because her appearance and inability to speak clearly. Janice conveyed the news to Dr. Turk's office, saying, "The recovery is so slow. Starting to get anxious."

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82. Her anxiety grew still when, by March 20, 2017 (more than a month after the procedures), she was "still not a hundred percent and I'm still nervous that when I bite into things I have to move my lower lip so I don't bite my lip. I also have a hard time flossing my teeth and now I find when I drink something it spills out of the corner of my mouth a bit. I am wondering if I should see a facial nerve specialist?"

83. Dr. Turk seemed to share Janice's concern, requesting that she send photos on a regular basis for months and prescribing her steroids and further recommending Botox to reduce swelling and improve her appearance. Yet he assured Janice time and again that "100% this is temporary. It is just hard to predict at what rate the muscles/nerves return to normal. . . . Sorry you have to go through this." On March 13, 2017, he claimed, "Could be just a few days now." But, by March 28, 2017, Dr. Turk admitted, "Thought it would be happening a bit faster . . . ." On April 3, 2017, he thought the "needle [had] start[ed] to move and the week after next sounds realistic." Nevertheless, he shared Janice's sense of helplessness, explaining that in the face of the serious physical and emotional impediments Janice was suffering, he had "meditated and sent good thoughts, and maybe the universe listened."

84. When, five weeks after the procedure which promised to require less than a week's downtime, Janice's face continued to droop, her lip paralysis persisted and talking, eating and drinking remained difficult and embarrassing, she sought a second opinion from Dr. Michael C. Kane, a well-regarded New York City plastic surgeon. Dr. Kane noted, "A[ssessment]: Prob[able] thermal marg[inal] mand[ibular] n[erve] injury." In other words, the aggressive parameters used by Dr. Turk resulted in just the sort of thermal injury we would expect from use of too much radio frequency over too long a period, failing to utilize the overlapping technique of which Dr. Mulholland has written in a peer-reviewed book chapter. He also observed that, at five weeks after the

procedure, Janice's neck remained red and swollen.

85. Janice experienced great pain and suffering as the result of the Fractora procedure and subsequent treatment. But the lasting effects are far more devastating. Dr. Kane expressed concern that Janice's nerve and muscle injury may be permanent. This concern has borne true. Her face remains droopy and her smile uneven eight months after the procedure. She also has permanent scarring on her neck.

86. When Janice's symptoms failed to improve as Dr. Turk indicated, she worried that they could be related to Multiple Sclerosis (referred to commonly as "MS"), a condition with which she was diagnosed in 2005 but for which she has not had a major flare up for ten (10) years. The possibility that she may have relapsed into an active state of the condition, an indication that the condition was worsening, caused Janice a great deal of anxiety and distress as a mother, a wife and a broadcaster. So, in addition to getting a second opinion from Dr. Kane, Janice also visited the physician caring for her MS. She also asked Dr. Turk his opinion. Both doctors agreed that the Fractora procedure, not the MS, caused Janice's symptoms.

87. While this offered Janice some solace, her inability to work—and the uncertainty of when or if she would be able to return to work— caused severe anxiety, panic attacks and depression common to those who have suffered a medical trauma. These serious conditions reflected a number of thoughts and feelings stirred by Janice's physical injuries. She feared she may not be able to return to work either on television or the radio, in which case, she would lose not only the fulfillment and sense of achievement and identity one gets from a successful career attained only after many, many years of hard work and dedication, but also, as the primary breadwinner, the financial stability of her family. She dreaded telling her supervisors, embarrassed for having undergone a cosmetic procedure and worried at how they would react to

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her inability to do her job after having just recently received the promotion to her dream job on Fox & Friends.

88. Her concerns about career made her desperate for assurance. She paid particular heed to Dr. Turk's promises that her injuries would resolve and was all the more disheartened when those promises proved untrue.

89. In total, Janice missed two months of work. Her humiliation at having been pulled off air by producers after her first attempt to return was compounded by the requirement that she submit to weekly screen testing, during which her producers would intensively scrutinize her face. They also shared the screen tests with others who were unaware of Janice's situation for feedback about her face and speech. This continued until, by her producers' estimation, the balance between their and viewers' desire to have Janice return to work and placing Janice back on air while still suffering effects from the procedure tipped in favor of the former.

90. Fox News continued to pay Janice's salary during her time off air; however, her career and career opportunities suffered. In broadcasting, dependability is paramount. Viewers crave continuity, consistency and routine. Although it was through no fault of her own, Janice disappointed both her producers and viewers when her injuries required a long leave of absence. She also missed career building opportunities during that time, including coverage of a major winter storm, attendance with her team at the State of the Union Address and multiple news pieces for which she would be the reporter. In addition, the injuries required that Janice cancel all other public appearances.

91. During this period, she also received thousands of emails from concerned viewers. They wanted to know why she was off air, when she would return, if she was sick and, more particularly, if she was experiencing a MS relapse. Viewers were not the only ones concerned that Janice may be struggling with MS. She learned of rumors among co-workers of exactly that.

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This was itself a source of worry because broadcasting, like so many careers in the public eye, places a great deal of emphasis on health, youth and beauty. Janice's career would suffer—she would be less marketable both to viewers and news groups—if she were even perceived as ill.

92. Consequently, Janice felt compelled to write and speak publicly about what happened to her to dispel this misperception. This compounded her feelings of embarrassment. It required that she again discuss the issue with Fox producers. It also required that she share with a large audience her decision to undergo an elective cosmetic procedure, something about which she felt a great deal of shame. She had not told even her closest friends and family members about the procedure. Now she was forced to tell everyone, including strangers.

93. Janice struggled personally with feelings of self-doubt and extreme self-consciousness. Her injuries markedly changed her physical appearance. For many months, she looked as though she may have suffered a stroke or some other serious illness. She feared she would never regain her former identity—or the ability to speak clearly and eat and drink without difficulty. Her lack of confidence changed the dynamics of daily life. She has retreated in large part from what had been a very active and happy social life. Janice lost sleep, lost weight and became easily irritable. She suffered terrifying panic attacks during which she could not breathe, shook, cried uncontrollably and felt nauseas.

94. These attacks, and her depression and anxiety in general, in turn, affected her husband and sons. From her husband's perspective, a loving one to be sure, the procedure had been completely unnecessary. He felt anger at the pain the injuries were causing his wife and family. Janice's sons were nothing short of traumatized by their mother's panic attacks and initial appearance after the procedure. At eight and six years old, their sense of security and contentment depended almost wholly on their mother's health and happiness. The change in her appearance—especially something so fundamental as her

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smile—also shook them to their core.

95. For her and her family's sake, Janice began counseling. While it has helped, she continues to struggle. She still receives emails from viewers, who point out that her smile remains crooked.

Plaintiff Mia Jones

96. Prior to the Fractora procedure performed by an aesthetician at the office of Dr. Paulino E. Goco, located in Nashville, Tennessee, on November 15, 2017, Mia was an extremely young-looking forty-nine (49) year old aesthetician and hair stylist. She is mother of two children, nine (9) and fifteen (15) years of age. She enjoyed an active work and social life in Nashville. Mia sought treatment only to refresh her skin, which was virtually wrinkle-free and healthy-looking.

97. Invasix representatives Heather Acquire and Trip Hutson sold the InMode machine to Dr. Goco. Acquire, Hutson and, Invasix trainer, Cheryl Hazing, visited with Mia and the other office aestheticians and staff in that process, explaining and demonstrating the procedures that can be performed by the machine. With regard to the Fractora, they claimed the procedure was an extremely safe, painless and non-invasive alternative to face lift and other energy based (laser) procedures. They also assured Mia the procedure was risk-free and would require little downtime. They did not reveal to Dr. Goco or his staff that, by that time, in late 2016-early 2017, no fewer than eleven other women had been burned and permanently disfigured by the Fractora procedure.

98. At the recommendation of Acquire, Hutson and Hazing, Dr. Goco had Mia and two other office aestheticians, Tricia King and Mandi Perry, trained to perform the Fractora procedure. Acquire, Hutson and Hazing did not disclose to Dr. Goco or to his staff that the FDA clearance for the Fractora machine was for physician's use only.

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99. Mia's injury occurred the third time she underwent the Fractora procedure. Tricia King and Mandi Perry, Mia's fellow aestheticians, performed the first Fractora treatment using the 24 pin coated tip for two, single pulse passes at 15 mj. Perry performed the second approximately six (6) weeks later, using the 24 pin coated tip for a single, double pulse pass at 20 mj. Mia tolerated those procedures well.

100. The third procedure, performed roughly six (6) weeks later, differed from the first two only in that King followed the first pass with a second, using the 60 pin tip at 30 mj. This third procedure left Mia's face extremely red and a little swollen even after using a cooling device. Her redness turned to scabbing of the forehead and cheeks. The condition of her face required Mia take three days off work after the third procedure.

101. Mia and King selected these parameters after training by Hazing and reference to the January 2015 Quick Reference Guide ("QRG"). This QRG indicates the "short 60 pin tip," is safe for use on "full face" to treat superficial, moderate and deep texture, tone and wrinkles. It also recommends energy parameters for the 60 pin tip of up to 62, the highest energy setting.

102. Given these indications—which were reiterated in the Invasix training—Mia and King understood the 60 pin tip is less aggressive than the 24 pin tip. However, Dr. R. Stephen Mulholland, the co-founder of Invasix and co-inventor of InMode/Fractora, testified in October 2015 that the 60 and 126 pin tips are more aggressive than the 24 pin tip counterpart in terms of the very adverse effects suffered by Mia, possible unintended changes in skin color and texture.

103. Moreover, had Invasix provided Dr. Goco the most updated QRG at the time of Mia's third procedure— the QRG dated March 2017—she would have seen that Invasix actually recommended against using the 60 pin tip for her Fitzpatrick Skin Type, Type IV. The March 2017 QRG also recommends

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the 60 pin tip be used at much less aggressive energy settings, never more than 30 mj.

104. After the fact, Wanda Cummings, an Invasix trainer, told Mia her injuries were the result of using the 60 pin tip given her skin Type IV. Cummings conclusion about the cause is corroborated by the March 2017 QRG.

105. Dr. Goco expressed frustration at Invasix's failure to provide him and his staff updated training information. In a January 22, 2018 email from him to Mia, Dr. Goco wondered, "Why did they not give us a notice [that the treatment instructions had changed] and update training information???" In the same email chain, Mia shares with Dr. Goco to what Wanda Cummings, the Invasix trainer, attributed her injuries:

106.

Dr. Goco on January 17, 2018	"Did she give any idea why that happened to you??? I think we should get [a]nother trainer out for every to get the latest parameters[.]
Mia on January 22, 2018 at 9:03 a.m.	***"[She said] I shouldn't have used a 60 pin on my face.*** The chart though said it was okay for type IV skin. Would it be okay if I ask her to come? She said she was going to pop by when she was near Nashville when I spoke with her." (Emphasis added)
Dr. Goco on January 17, 2018 at 9:24 a.m.	"Yes, [i]t would be nice to have her come by and refresh everyones['] training. Why did they not give us a

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	notice and update the training notice information???"

107. Again, the procedure left Mia's face extremely red and swollen. Her face then scabbed to the point Mia could not work for three days. Mia's scabbing ultimately turned to scarring over her entire face. It resulted in volume loss in Mia's cheeks. The skin in Mia's cheeks, around her smile lines and under her eyes is thin, loose and crepey. In addition, Mia suffered collapsed pores and other changes in her skin texture.

108. Mia has seen multiple doctors to address her disfigurement. Dr. Natalie Curcio has performed a few laser genesis treatments, all to no avail. Mia has also seen (and, in some cases, incurred consultation charges for) Drs. Williams Stebbins, John Binglam, Brian Beisman and Steven Bengelsdorf. She has also purchased medications, ointments and other over the counter treatment products.

109. Mia has suffered emotionally, too. She is a young, beautiful woman who, until her injuries, enjoyed the good fortune of healthy, young looking and virtually wrinkle and damage-free skin. The changes in Mia's face add ten to fifteen years to her appearance and cause her to look less healthy. The loss of volume and crepey skin even appear to be smoker's lines. This is particularly hurtful to Mia, who makes her living in the aesthetic and health industry.

110. As a result of her disfigurement, Mia has experienced extreme anxiety, depression, sleeplessness, loss of appetite, irritability and, worst of all, a significant decrease in her self-esteem. She finds mornings particularly difficult. She often suffers panic attack symptoms in the mornings, including loss of breath, rapid heartbeat and a sense of dread. Mia lost more than ten (10) pounds from her already small frame (she weighed as little as 116, down from her normal weight of 128 pounds).

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111. Mia's inability to focus on work has resulted in loss of clients, loss of revenue in the form of gratuities from clients and the loss of credibility with her co-workers and Dr. Goco. She estimates her total lost earnings to be $8,100, which represents loss of nine (9) long-term clients who Mia had previously seen every six to eight weeks for roughly $150/appointment in services.

112. She has also become obsessive in her research of the Fractora procedure and doctors who specialize in treating injuries like hers. She has extreme anxiety about undergoing additional treatments given her experience. She will only feel comfortable using the best doctors in the area of scar treatment, whom she believes to be Dr. Peter Rullan in Chula Vista, CA and Dr. David Lim in Brisbane, Australia.

113. Dr. Rullan has recommended 2-3 erbium ($500 per treatment) and at least 3 Vbeam ($300 per treatment) laser treatments, 1-3 CROSS (Chemical Reconstruction of Skin Scars) ($100-$250 per treatment, depending upon provider) treatments and 2 vials of Sculptra filler ($1,250 per vial). The laser treatments will have to be repeated multiple times and the Scuptra filler will require lifelong retreatment.

114. Dr. Lim has recommended approximately 3 Fraxel 1927 and Co2 laser treatments for an estimated cost of $3,000-$5,000.

115. Thus, the total estimated cost of immediate (within a year) future treatments is $3,000-5,650, with another $10,000 for Scuptra filler replacement every 3 years for 15 years—a total that will exceed $65,650 in Mia's lifetime.

116. Mia's lack of confidence has also affected her daily life. She has retreated from what had been a very active and happy social life. She stopped attending church. She has yet to return to a singles-type social group in Franklin, TN. She even missed her son's soccer games, fearing what the other soccer moms would think. Mia nearly passed on a trip to Italy she and her friends had

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been planning (and for which she had paid) months in advance. As it was, she kept her plans but the entire trip—like all Mia's social and professional experiences since the injuries—was shrouded in the sadness and grief she now feels all the time.

117. For the first time, Mia began seeing a counselor, Tammy Dickerson, for symptoms of medical treatment-related Post Traumatic Stress Disorder, anxiety and depression. Her treatment has been helpful but, alas, her symptoms persist. In fact, had it not been for her sessions with Lee, Mia believes she would have become completely disabled. These sessions have come at great expenses, more than $1,600, and time off work.

118. Altogether, Mia's out of pocket expenses exceed $3,771.36. Her total economic damages alone total more than $75,000.

Federal Law Does not Preempt Plaintiffs' Claims

119. Plaintiffs' claims are not preempted by federal law for multiple reasons. As a preliminary matter, the FDCA preemption provision applies only to state law claims that create different or additional requirements and relate to either safety and efficacy of the device or some other device specific requirement. 21 U.S.C. § 360k(a). The FDA 510(k) clearance process, also called a "premarket notification process," focuses on whether the Product is substantially equivalent to a predicate product and does not require the rigorous "premarket approval" process by which the FDA determines the safety and efficacy of other Class III medical devices. To the contrary, "Section 510(k) clearance is not equivalent to FDA 'approval' of a device." *U.S. v. Medtronics, Inc.*, 2017 US DIST. LEXIS 153887, at *6. Courts have found preemption does not apply to common law failure to warn product defect claims in 510(k) clearance cases. *See e.g., Medtronics, Inc. v. Lohr,* 518 U.S. 470, 481, 484-98, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

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120. Similarly, regulation implementing the FDCA clarifies the Act's preemption provision, which "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. § 808.1(d). The Ninth Circuit borrowed language from the Eighth Circuit in describing the "narrow gap" through which a state law claim must fit to avoid express preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because of the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman [Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 350, 121 S. Ct. 1021, 148 L. Ed. 2d 854 (2001)*].*" *Perez v. Nidek, Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

121. Plaintiffs' state law claims fall squarely within this gap, "parallel or 'genuinely equivalent' to federal law," and, thus, fall outside the express preemption of the FDCA.[12] *See Stengal v. Medtronics, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (holding state common law claims, including negligence, premised on Medtronics failure to report adverse events to the FDA or otherwise warn of prior failures of the device not preempted because the state paralleled federal law inasmuch as it incorporated federal law as setting the standard of care); *Houston v. Medtronics, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) (holding fraud-based and express warranty claims predicated on manufacturer's promotion of off label use without disclosing the risks associated with that use to fall outside express and implied preemption).

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[12] California law applies as Invasix's wrongful conduct emanates in California. *See, e.g., Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 1207, 127 Cal. Rptr. 3d 185, 254 P.3d 237 (2011) (holding California's consumer protection laws "reach[] any unlawful business act or practice committed *in California*").

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122. State law claims fall outside implied federal preemption if not barred by express preemption and "moored in traditional state common law that exists independently from the FDCA." *Houston*, 957 F. Supp. 2d at 1179. California consumer protection laws create a duty independent of the FDCA on manufacturers to refrain from false and deceptive advertisement even when the truth of that advertisement "may be generally within the purview of the FDA." *See In re Epogen & Aransep Off-Label Marketing & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1291 (C.D. Cal. 2008) ("[I]nsofar as Plaintiffs can identify specific representations by Defendants that are literally false, misleading, or contain material omissions, the claims are actionable" under state and federal consumer protection laws.). Thus, Plaintiffs' state law claims are not impliedly preempted.

FIRST CAUSE OF ACTION

(Breach of Express Warranty)

123. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

124. The owners of the Product used on Plaintiffs formed a contract with Defendant at the time they purchased the Products. Plaintiffs are in privity with those owners. The terms of that contract include the promises and affirmations of fact made by Defendant on the Product's labeling and through Defendant's promotional activities, marketing and advertising. The affirmations of fact made in the promotional activity, marketing and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and Defendant.

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125. The affirmations of fact made by Defendant include, but are not limited to, claims:

(a) Product is safe; effective; safer, more effective and requires less recovery time than alternative procedures such as face lifts, laser surgeries and chemical processes;

(b) Product is recommended by physicians with no financial interest in promoting the Product;

(c) Product "promotes more superficial ablation and is more focused on non-coagulative dermal residual heat" than alternative procedures; "relatively comfortable;" "a complete single treatment solution for aging patients;"[13]

(d) "Fractora is considered a non-invasive skin resurfacing and restoration treatment that has been approved by the FDA and Health Canada;" "Fractora does a better job [than traditional fractional procedures] because it goes deeper and combines ablative and non-ablative RF;" "[Fractora's] RF influences all of the skin underneath, not just where the pins penetrate and heat the skin [unlike traditional laser fractional therapy;" Fractora's secondary heating next to where the pins penetrate and heat the skin is better controlled than with traditional laser fractional therapy;

(e) "Fractora is the most advanced fractional radio-frequency treatment;" "Fractora is light years ahead of traditional CO2 laser or Fraxel;" "Part of the advantage of Fractora is the ability to treat the neck;" Fractora can be safely performed by a non-physician "technician;" using test spots is optional or only for patients "worried about

[13] *See* "Fractora: A Novel Method for Deep Radio-Frequency Fractional Resurfacing and Total Skin Rejuvenation" white paper included in promotional materials provided at demonstrations conducted by Dr. Mulholland.

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discomfort and healing;" Fractora "allows patients to look 10-15 years younger;" Fractora is "industry leading transformation" and

(f) "Stacking pulses in the same site may improve the results of tightening and ablation. It is safe to stack with the 24 pin tip . . . ."

126. Plaintiffs or the Product owners have performed all conditions precedent to Defendant's liability for breach of its express warranties.

127. Defendant breached express warranties about the Product and its qualities because its statements about the Product were false and the Product does not conform to their affirmations and promises. Plaintiffs would not have undergone the Fractora procedure had they known the true nature of the Product and procedure and Defendant's misstatements regarding the Product.

128. As a result of Defendant's breach of warranty, Plaintiffs have been damaged in the amount of the purchase price of the Fractora procedure and any consequential damages resulting from the procedure, including the cost to treat the injuries and scarring caused by the Product.

SECOND CAUSE OF ACTION

(Breach of Implied Warranty)

129. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

130. At all times relevant hereto, there was a duty imposed by law which requires that a manufacturer or seller's product be reasonably fit for the purposes for which such products are used, and that product be acceptable in trade for the product description.

131. Notwithstanding the aforementioned duty, at the time of delivery, the Products used on Plaintiffs were not merchantable because they contain defect(s) that cause unintended injuries, such as burning, scarring and nerve damage, even when employing device settings and techniques found on the Product labeling or in promotions of the Product by Defendant, and do not

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otherwise perform as represented.

132. Plaintiffs notified Defendant the Product was not merchantable within a reasonable time after the defect manifested to Plaintiffs and other consumers.

133. As a result of the non-merchantability of the Product, Plaintiffs and other consumers sustained damages.

THIRD CAUSE OF ACTION

(Fraud--Violation of California Unfair Competition Statute ("CUCS"))

Cal. Bus. & Prof. Code § 17200 et seq.

134. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

135. Plaintiffs, as purchasers of the Fractora procedure performed with the Product, are consumers within the meaning of the CUCS given that Defendant's business activities involve trade or commerce, are addressed to the market generally and otherwise implicate consumer protection concerns.

136. As detailed above, Defendant, through its promotional activities, advertisements and Product labeling, used false advertising to sale the Product. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct violates CUCS: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6) promotion of use of the

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Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA; and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can be achieved with alternative procedures.

137. Defendant also knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiffs and to the users of the Products used on Plaintiffs knowing that the users and Plaintiffs would rely on the promotional materials, advertisements and labeling in, on the part of the Plaintiffs, purchasing the Fractora procedure and, with regard to the users, purchasing and using the Products.

138. Once defects in the Product and its tendency to cause unintended injuries despite use as instructed by Defendant became apparent to Defendant, Defendant had a duty to disclosure that fact—and adverse events— because this risk would be a material fact in the decision making process of Plaintiffs and those performing the Fractora procedure, and, without Defendant's disclosure, Plaintiffs and those performing the Fractora procedure would not necessarily know that there is such a risk.

139. Defendant intended that Plaintiffs and those performing the Fractora procedure would rely on the continued deception by purchasing the Fractora procedure and using the Product, unaware of these material facts and omissions. Defendant further knew that Plaintiffs and those performing the Fractora procedure would continue to rely on Defendant's representations and silence as to any known risk of unintended injuries as evidence that the Product was safe and would perform as represented. Defendant's wrongful conduct, which emanates in California, where Defendant maintains is principal and sole

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place of business, constitutes breaches of express and implied warranties, and, as such and independently, constitutes consumer fraud within the meaning of the CUCS.

140. Defendant's material non-disclosure constitutes an unconscionable commercial practice, deception, fraud, false promise, misrepresentation and/or omission of material facts as to the nature of the goods in violation of the CUCS.

141. Defendant is the producing and proximate cause of Plaintiffs' injuries.

FOURTH CAUSE OF ACTION

(Fraud—Violation of California False Advertising Law ("CFAL") Bus. & Prof. Code § 17500 et seq.)

142. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

143. Plaintiffs, as purchasers of the Fractora procedure performed with the Product, are consumers within the meaning of the CFAL given that Defendant's business activities involve trade or commerce, are addressed to the market generally and otherwise implicate consumer protection concerns.

144. Defendant knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiffs and to the users of the Products used on Plaintiffs knowing that Plaintiffs and users would rely on the promotional activities, advertisements and labeling in, on the part of the Plaintiffs, purchasing the Fractora procedure, and, with regard to the users, purchasing and using the Products. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct violates CFAL: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or

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fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6) promotion of use of the Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA; and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can be achieved with alternative procedures.

145. Once the defects in the Products and their tendency to cause unintended injuries despite use as instructed by Defendant became apparent to Defendant, Defendant had a duty to disclosure that fact—and adverse events—because this risk would be a material fact in the decision making process of Plaintiffs and those performing the Fractora procedure, and, without Defendant's disclosure, Plaintiffs and those performing the Fractora procedure would not necessarily know that there is such a risk.

146. Defendant intended that Plaintiffs and those performing the Fractora procedure would rely on the continued deception by using and purchasing the Product and performing and undergoing the Fractora procedure, unaware of these material facts and omissions. Defendant further knew that Plaintiffs and those performing the Fractora procedure would continue to rely on Defendant's representations and silence as to any known risk of unintended injuries as evidence that the Product was safe and would perform as represented. Defendant's wrongful conduct, which emanates in California, where Defendant

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maintains is principal and sole place of business, constitutes breaches of express and implied warranties, and, as such and independently, constitutes false advertising within the meaning of the CFAL.

147. Defendant's material non-disclosure constitutes false advertising in violation of the CFAL.

148. Defendant is the producing and proximate cause of Plaintiffs' injuries.

FIFTH CAUSE OF ACTION

(Fraud—Common Law)

149. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

150. Defendant knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiffs and to the users of the Products used on Plaintiffs knowing and intending that Plaintiffs and users would rely on the promotional activities, advertisements and labeling in, on the part of the Plaintiffs, purchasing the Fractora procedure, and, with regard to the users, purchasing and using the Products. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct constitutes common law fraud: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6)

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promotion of use of the Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA; and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can be achieved with alternative procedures.

151. Defendant's fraud is the proximate cause of Plaintiffs' injuries.

SIXTH CAUSE OF ACTION

(Negligence, Negligence Per Se and Gross Negligence)

152. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

153. Defendant owed Plaintiffs a duty to use due care in their development, testing, planning, design, marketing and sale of the Product.

154. Under the FDCA, CUCS, CFAL and the applicable common law, Defendant owed Plaintiffs a duty of care to refrain from the false, misleading or fraudulent off-label promotion and labeling of the Product. Under the FDCA, CUCS, CFAL and the applicable common law, Defendant also owed Plaintiffs a duty to report adverse events related to use of the Product. Finally, under the FDCA, CUCS, CFAL and the applicable common law, Defendant owed Plaintiffs a duty to refrain from promoting use of the Product by non-physicians. The statutory schemes of the FDCA, CUCS and CFAL are designed to protect vulnerable patients like Plaintiffs and, therefore, set the standard of care in these regards.

155. Defendant breached these duties by (1) failure to exercise due care in producing, processing, manufacturing, distributing and/or offering for sale the Product and, therefore, selling the Product in a defective condition that was unsafe for use as promoted by Defendant, namely the failure to warn; (2) false,

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misleading or fraudulent off-label promotion of the Product; (3) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins; (4) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product; and (5) promoting use of the Product by non-physicians.

156. Defendant further breached its duty of care to Plaintiffs by failing to use sufficient quality control, perform adequate research or testing, proper manufacturing, production or processing, and failing to take sufficient measures to prevent the Product from being offered for sale in an unsafe and hazardous form.

157. In addition, Defendant breached its duty of due care by failing to properly and adequately inform consumers, including Plaintiffs, health care providers and the FDA once risks of unintended injuries such as burns, scars and nerve damage were brought to the Defendant's attention.

158. Defendant knew, or in the exercise of reasonable care should have known, that the Product presents an unacceptable risk to consumers, including Plaintiffs, and would result in damages that were foreseeable and reasonably avoidable.

159. As a direct and proximate result of Defendant's above-referenced negligence, negligence per se and/or gross negligence, Plaintiffs have suffered and are entitled to recover damages, both compensatory and punitive.

SEVENTH CAUSE OF ACTION

(Strict Liability)

160. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

161. Defendant is the producer, manufacturer, marketer, distributor and/or seller of the Product.

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162. The Product is defective in design or formulation due to inconsistent and inadequate instructions/warnings and the promotion of off-label use of the Product employing aggressive settings and techniques in order to exaggerate the effectiveness of the Product while failing to disclose the dramatic increase in risks of unintended injuries when using the Product in such an aggressive manner.

163. The Product is also defective due to inadequate post-market instruction/warnings because, after Defendant knew or should have known of the risk of injury from the Product, Defendant failed to immediately provide adequate instruction/warnings and report adverse events to Plaintiffs, health care providers and the FDA.

164. As the direct and legal result of the defective condition of the Product as produced, manufactured, designed, marketed, distributed and/or sold by Defendant, and of the negligence, carelessness, other wrongdoing and actions of Defendant described herein, Plaintiffs suffered damages.

ATTORNEYS' FEES, EXPENSES AND COSTS

165. Plaintiffs hereby incorporate the above allegations by reference as though fully set forth herein.

166. Plaintiffs have been forced to secure the assistance of counsel to protect their legal rights and mitigate their damages as a result of the Defendant's wrongful conduct.

167. Having made proper presentment and provided actual and sufficient notice of their claims to Defendant, Plaintiffs seek recovery of their reasonable attorneys' fees, expenses and costs pursuant to all applicable statutes, regulations and agreements.

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PRAYER

WHEREFORE Plaintiffs pray for Judgment against Defendant as follows:

1. For an award of actual, consequential and punitive damages according to proof;
2. For an award of reasonable attorneys' fees, costs and pre- and post-judgment interest; and;
3. For all other relief to which they may be justly entitled.

Respectfully submitted,

CHRISTIANSEN DAVIS, LLC
ESENSTEN LAW

By: /s/ Robert L. Esensten
Amy E. Davis
Robert L. Esensten
ATTORNEYS FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury.

Respectfully submitted,

CHRISTIANSEN DAVIS, LLC
ESENSTEN LAW

By: /s/ Robert L. Esensten
Amy E. Davis
Robert L. Esensten
ATTORNEYS FOR PLAINTIFFS

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